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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,086	02/24/2000	Linda S. Mansfield	MSU 4.1-458	4724

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	14

DATE MAILED: 06/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Advisory Action

Application No.	Applicant(s)
09/513,086	Mansfield, L.S. et al.
Examiner	**Art Unit**
Joseph T. Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *May 24, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: *4-9, 13-17, 45, 46, 49, and 50*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☒ Other: *Claims 23-28 were canceled in paper number 11 (mailed Nov 15, 2001).*

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Attachment

Applicants after final amendment mailed May 24, 2002, paper number 13 has been entered.

Applicants remarks regarding Bigbie *et al.* WO 01/80885 is noted.

Section 5(e):

Regarding the written description rejection made under 35 USC 112, first paragraph, Applicants argue that the claims are fully enabled because the compositions are drawn to using the proteins in toto, not particular epitopes, and only administration of the proteins would be necessary. It is argued that the skilled artisan need only isolate the antigens and administer said proteins. Further, it is noted that infected horses generate antibodies to these antigens, though the antibodies made are non-inhibitory.

Regarding the enablement rejection made under 35 USC 112 first paragraph, Applicants argue that because horses with EPM have antibodies against the antigens and the fact that some of the horse develop immunity, a vaccine comprising these antigens could provide immunity. Applicants note that ' vaccine or composition does not need to provide good efficacy, it merely has to enable some horses to develop immunity' (Applicants' amendment, middle of page 8). See Applicants' amendment pages 5-11. Applicants arguments have been fully considered but not found persuasive.

First, it is noted that neither the polynucleotide nor protein sequence for the claimed 16 and 30 kDa antigens are taught in the instant specification or known at the time of filing. Given the specific sequence of any 16 and/or 30 kDa protein known in the art, one of skill would not know if it were the instantly claimed proteins in light of the lack of teaching in the instant specification. The only distinguishing feature of the proteins/antigens claimed is their general molecular weight in a SDS PAGE gel which fails to meet the written description requirement for the specific vaccine instantly claimed. Absent any specific sequence, it is impossible to generate a recombinant form of said proteins. Even if one were to isolate and fully characterize these proteins, as noted by Applicants, the only immune response mounted to these antigens normally was the detection of a non-inhibitory antibody in the serum (middle of page 6 and Liang *et al.*). Since these antigens did not produce an immunity with any affect as evidenced by the art, and the specification provides no further guidance besides to deliver these antigens, the specification fails to teach why or how the instantly claimed methods would function as a vaccine and produce a protective immune response. In light of the failure of the art to produce a protective immune response to the antigens and the failure of the present disclosure to describe said antigens in any detail for use in the instantly claimed methods, it would constitute undue experimentation make and use the instantly claimed products and methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Joseph T. Woitach